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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,631	08/05/2003	Ellen M. Beasley	CL001078DIV	6370

25748 7590 05/31/2006

CELERA GENOMICS
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,631	BEASLEY ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3, 24-38* is/are pending in the application.

4a) Of the above claim(s) *1,2,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Maher Haddad, Art Unit 1644, Technology Center 1600.

2. Claims 1-3, 24-38 are pending.

3. Applicant's election with traverse of Group II, claim 3, (now claims 3, and 24-36) directed to an antibody that selectively binds to a polypeptide of SEQ ID NO: 2, filed on 3/16/06, is acknowledged.

Applicant's traversal is on the grounds that examination of Group II inherently includes a search of the amino acid sequence of the polypeptides claimed in Group I. This is not found persuasive because the specific antibodies/polypeptide are recognized divergent subject matter. In addition, the polypeptides and antibodies are distinct because their structures are different and are therefore capable of separate manufacture, use and sale. Therefore these products are distinct and independent, and searches of all groups would place an undue burden upon the examiner due to the distinct and divergent subject matter of each Group. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 1-2 and 37-38 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

5. Claims 3 and 24-36 are under examination as they read on an antibody that selectively binds to a polypeptide of SEQ ID NO: 2.

6. The specification on page 1 should be amended to reflect the status of 09/819,607 and the relationship between 09/819,607 and the instant application.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 31-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The phrase "a composition comprising the antibody of claim 3/24/25/26 and a pharmaceutically acceptable carrier" claimed in claims 31-34 represent a departure from the specification and the claims as originally filed.

Applicant's amendment filed 3/16/06 does not point to the specification for support for the newly added limitation "a composition comprising the antibody of claim 3/24/25/26 and a pharmaceutically acceptable carrier" as claimed in claims 31-34. However, the specification does not provide a clear support such limitations. The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e2) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(e1) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

10. Claims 3 and 24-34 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 2000/73469 (Dec. 2000).

The `469 publication teaches an antibody (e.g. monoclonal) that binds to a kinase polypeptide of published SEQ ID NO: 124 (published claims 26-28 on ps. 148-152 and p. 52, lines 9-10, p. 90 in particular). In addition, the `469 publication teaches antibody raised against KSRDNSRDSSQSEND amino acids 289-303, T(R)EKLKRSQDLPREPLP amino acids 322-336 and RGWRPYDIHS amino acids 173-182 of claimed SEQ ID NO: 2 (see page 126 and table 13, row 2-4 in particular). Published SEQ ID NO: 124 has a 100% sequence identity to claimed SEQ ID NO: 2. While sequence alignment shows that the published SEQ ID NO: 124 is 99.5% identical, however, the amino acid difference between the claimed and referenced sequence is H136X. However X can be any amino acid including H. Further, given the high sequence

identity/homology between the referenced/claimed polypeptides; the referenced antibodies would have the inherent property of binding claimed SEQ ID NO: 2 in the absence of objective evidence to the contrary. The `469 publication teaches that for cells harbored within the organism, many techniques exist in the art to administer compounds, including oral, parenteral, dermal, injection, and aerosol applications. For cells outside of the organism, multiple techniques exist in the art to administer the compounds, including cell microinjection techniques, transformation techniques and carrier techniques (see p. 62, lines 8-15 in particular). Therefore, in order for the antibodies to, for example, be injected, it must be in a composition with a carrier. Finally, the `469 publication teaches that antibodies may be detectably labeled. Antibodies can be detectably labeled through the use of radioisotopes, affinity labels (such as biotin, avidin, and the like), enzymatic labels (such as horse radish peroxidase, alkaline phosphatase, and the like) fluorescent labels (such as FITC or rhodamine, and the like), paramagnetic atoms, and the like (see p. 91, lines 13-18 in particular).

The reference teachings anticipate the claimed invention.

11. Claims 3 and 24-36 are rejected under 35 U.S.C. 102(e1) as being anticipated by US. 2006/0068481.

The `481 publication teaches and claims an antibody which specifically binds to a polypeptide of published SEQ ID NO: 12 (see published claim 10 in particular). Published SEQ ID NO: 12 has 100% sequence similarity to claimed SEQ ID NO: 2 at position 51-350 of published SEQ ID NO: 12. The `481 publication teaches that antibodies to PKIN can also be generated using methods that are well known in the art. Such antibodies may include, but are not limited to, polyclonal, monoclonal, chimeric, and single chain antibodies, Fab fragments, and fragments produced by a Fab expression library (see ¶65 and 196 in particular). In addition the `481 publication teaches a composition which generally comprises an active ingredient formulated with a pharmaceutically acceptable excipients, wherein the compositions can consist of antibodies to PKIN (see ¶224 in particular). The `481 publication teaches antibodies may be used with or without modification, and can be labeled by covalent or non-covalent attachment of a reporter molecule (e.g., detectable substance). A wide variety of reporter molecules (see ¶233 in particular).

The reference teachings anticipate the claimed invention.

12. Claims 3 and 24-36 are rejected under 35 U.S.C. 102(e2) as being anticipated by US. Pat. No. 6,638,721.

The `721 patent teaches anti-kinase polyclonal and monoclonal antibodies that bind a kinase protein. The `721 teaches an isolated kinase polypeptide can be used as an immunogen to generate antibodies that bind kinase proteins using standard techniques for polyclonal and monoclonal antibody preparation. The full-length kinase protein can be used or, alternatively, the invention provides antigenic peptide fragments of the kinase protein for use as immunogens. The

antigenic peptide of the kinase protein comprises at least 8, preferably 10, 15, 20, or 30 amino acid residues of an amino acid sequence shown in SEQ ID NO: 14 and encompasses an epitope of a kinase protein such that an antibody raised against the peptide forms a specific immune complex with the kinase protein (see col. 39 line 48 to col. 42 line 35 in particular). Claimed SEQ ID NO: 14 has 100% sequence similarity to claimed SEQ ID NO: 2 at position 51-419 of published SEQ ID NO: 14. The `721 publication teaches that detection can be facilitated by coupling the antibody to a detectable substance (see col., 41, lines 28-29 in particular). Also, the `721 patent teaches that antibodies can be polyclonal, or monoclonal. An intact antibody, or a fragment thereof (e.g., Fab or F(ab')2) can be used (see col., 57, lines 65-66 in particular). Lastly, the `721 patent teaches compositions comprising anti-kinase antibodies of the invention and a pharmaceutically acceptable carrier (see col., 47, lines 50-58 in particular).

The reference teachings anticipate the claimed invention.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2000/73469 in view of Owens *et al.*

The teachings of WO `469 publication have been discussed, supra. Further, the `469 publication teaches the term "antibody fragment" refers to a portion of an antibody, often the hyper variable region and portions of the surrounding heavy and light chains, that displays specific binding affinity for a particular molecule. A hyper variable region is a portion of an antibody that physically binds to the polypeptide target (see p. 53 lines 24-28 in particular). In addition, the `469 publication teaches that routine methods known to those skilled in the art enable production of antibodies or antibody fragments, in both prokaryotic and eukaryotic organisms (see p.54, lines 6-9 in particular).

The claimed invention differs from the reference teaching only by the recitation of a Fab fragment, a $F(ab')_2$ fragment or a Fv fragment in claims 35-36.

Owens *et al* teach the modification of murine antibodies such as a chimeric antibody, a single chain antibody, a Fab fragment, a $F(ab')_2$ fragment or a humanized antibody antibodies monoclonal antibody technology, chimeric, single chain, Fab fragments, and $F(ab')_2$. Owens *et al* further teach antibody fragments are the reagents of choice for some clinical applications (see the entire document).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to produce the monoclonal antibody taught by Bendayan as chimeric, humanized antibody, Fab and $F(ab')_2$ fragments taught by the Owens *et al.*

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the antibody fragments are the reagents of choice for some clinical applications as taught by Owens *et al.*

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expection of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 15, 2006

Maher Haddad

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600